SOP
Disinfection of Re-usable Medical Devices

Ministry of Health and Wellness
MAURITIUS

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Approval Form

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STANDARD OPERATING PROCEDURE FOR THE DISINFECTION OF RE-USABLE MEDICAL DEVICES			
	NAME	**SIGNATURE**	**DATE**
AUTHORIZED BY	*Permanent Secretary* *Mrs. Z. Lallmahomed*	✓	19/03/25
APPROVED BY	*Ag. Director-General Health Services* *Dr A. Dinassing*	✓	11/03/25
	Ag. Director Health Services for Public Health *Dr M. F. Khodabocus*	✓	11/03/25

AUTHORS

Mrs. B. Du Toit (IPC Nurse and Consultant from South Africa).

PEER REVIEW

Dr D. Nuckchady (Specialist in Internal Medicine and Infectious Diseases).

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Standard Operating Procedure for the Disinfection of re-usable Medical Devices

Challenges faced

During visits in July 2024 to the five regional hospitals, it was noticed that re-usable medical devices are often disinfected without prior cleaning. This practice can lead to inadequately decontaminated medical devices that contribute to the transmission of pathogens. Inadequate cleaning further leads to biofilm formation, which makes disinfection ineffective.[1] Antiseptics such as Savlon and chlorhexidine gluconate are routinely used to clean medical devices before they are disinfected with alcohol, hypochlorite (Javel) or ortho-phthalaldehyde (OPA). Antiseptics are meant for skin disinfection and should never be used as an environmental disinfectant.[1,2,3] Antiseptics and disinfectants are also not detergents and cannot break the surface tension of the water, which enable cleaning. Both alcohol and hypochlorite are inactivated by organic material which makes it ineffective if the devices have not been cleaned properly. [2,3,4]

Purpose

All healthcare workers involved in the decontamination of re-usable medical devices in the public sector must adhere to the Standard Operating Procedure (SOP) to ensure adequately decontaminated medical devices that are safe to use on patients.

This SOP has to be read in conjunction with the SOP for the ***Routine environmental cleaning of healthcare facilities*** and the ***National Guidelines on Infection Prevention and Control.***

Definitions:

Antiseptic: A chemical substance that inhibits the growth of micro-organisms. It is non-toxic and is safe to use on living tissue.[2]

Cleaning: Removal, usually with a detergent and water or enzymatic cleaner and water, of visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.[3]

Decontamination: Removes soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard.[4]

Detergent: A cleaning agent that increases the ability of water to penetrate organic material and break down greases and dirt. They consist out of hydrophilic component and a lipophilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.[2]

Disinfectant: An antimicrobial agent that destroys pathogens but not necessarily bacterial spores. Because it has an adverse effect on living tissue.[2,3]

Disinfection: Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily bacterial spores.[3]

Sterilization: A validated process used to render a product free of all forms of viable microorganisms, including bacterial spores.[3]

Key points

1. Re-usable medical devices must be cleaned and disinfected or sterilized after use to prevent the transmission of infections.
2. Using detergents for cleaning of surgical equipment is an essential first step for effective removal of organic matter, reducing bioburden, and preparing the instruments for disinfection or sterilization.
3. A risk assessment of all used medical devices has to be done to establish the level of decontamination required. This is referred to as "Spaulding classification'' and the purpose is to categorize a re-useable medical device according to its intended use and the subsequent level of reprocessing required to render the device safe to use again.[4]
4. Re-usable medical devices are categorized as critical, semi-critical and non-critical.

Risk Category	Recommended level of decontamination	Examples of medical devices
High (Critical items) Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, syringes, needles
Intermediate (Semi-critical) Items in contact with mucous membranes, non-intact skin and body fluids	Disinfection (High Level)	Respiratory equipment, non-invasive flexible endoscopes, re-usable bedpans and urinals
Low (non-critical) Items in contact with intact skin	Cleaning	Blood pressure cuffs, stethoscopes, thermometers

Adapted from the World Health Organization. Manual for decontamination[4]

5. In addition to Spaulding's classification, important considerations when deciding on a decontamination method are:
    - Patient susceptibility
    - Tolerance of the device/type of material being re-processed
    - The nature of contamination/micro-organisms present
    - Time available for re-processing
    - The intended use of the medical device
    - The risk posed to patients and healthcare worker
    - Cost of processing
    - Availability of processing equipment[2]
6. **Always follow the recommendations of the manufacturer for decontamination.**

7. To ensure effective disinfection and adequate penetration of the disinfection solution, all visible organic matter must be removed by first clean the device with a detergent and water prior to disinfection:
    - Antiseptics and disinfectants do not make dirt safe.
    - Dirt provides bacteria with a protective coat, and the disinfectant may not penetrate sufficiently to inactivate the bacteria.
    - Organic matter de-activates some disinfectants.
8. Organic matter may be more difficult to remove after exposure to chemical or heat disinfectants.
9. Never use antiseptic solutions such as Savlon or chlorhexidine to clean dirty medical devices.
10. Hypochlorite is a disinfectant and should not be used to clean dirty medical devices.
11. It is essential that the disinfectant is stored in the correct container and when used, is compatible with the item to be disinfected, according to the manufacturer's guidelines.
12. Disinfectants have to be re-constituted according to the Manufacturer's instructions.
13. Write the date of re-constitution on the container/record it in a register.
14. Never top-up disinfectants.
15. Always clean disinfectant containers with soap and water and heat disinfect it, prior to refilling. It must be clean and completely dry to prevent the multiplication of micro-organisms in the solution. **Refer: National Standard Operating Procedure: *Cleaning of re-usable medical devices*** and ***National IPC Guideline***
16. Manufacturer Safety Data Sheets (MSDS) must be readily available and not older than five years. The MSDS provides information about the active ingredient of chemicals as well as the safety precautions that should be taken in the event of accidental exposure.
17. Always make sure that containers with disinfectant are closed with the lid on and not in direct sunlight.
18. Different disinfectants should never be mixed together as they may inactivate each other's active ingredients.
19. A record must be kept of all items disinfected with a high-level disinfectant.[2,3,4,]

Steps to be followed

1. Ensure that the device to be cleaned is compatible with the chemical solutions used in the facility.
2. Donn the appropriate personal protective equipment (PPE) e.g. disposable gown/apron, utility gloves, facial protection.
3. Always adhere to Standard and Transmission-based precautions. (Refer: *National IPC Guideline*)
4. Prepare the enzymatic detergent by diluting it according to the manufacture's recommendation. Use the appropriate measuring devices. Never use Savlon, hypochlorite (Javel) or chlorhexidine to "wash any device".
5. Ensure that the water temperature is correct according to the manufacturer's instruction. Avoid too

hot water.

6. Remove gross soiling before submerging the device.
7. The instrument must be dismantled or opened as necessary to ensure all of its parts are adequately cleaned.
8. Completely submerge immersible items during the cleaning process to minimize aerosolization and to assist with cleaning.
9. Remove gross soil with brushes and single-use cloths.
10. First remove the gross soil and organic material from devices that cannot be submerged and then wipe it with a cloth damped with water and detergent.
11. Once the devise is clean, allow it to dry completely and then disinfect.[2,4]

Decontamination guidelines for equipment

1. Always first clean all used medical devices with an enzymatic cleaner before it is disinfected.
2. Do a risk assessment based on Spaulding's classification.
3. **Always consult the manufacturer's instructions.**[3]
4. Ensure the correct contact time for the disinfectant.[2,3,4]
5. Ensure that, at a minimum, noncritical patient-care devices are cleaned and disinfected when visibly soiled after used and cleaned after each patient use.
6. If dedicated, disposable devices are not available, disinfect noncritical patient-care equipment always after use on a patient who is on contact precautions before using this equipment on another patient.[3]
7. Store disinfected medical devices in a clean and dry area to prevent re-contamination.

Manufacturer's instructions for product, concentration and contact time must always be followed			
Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Aeroneb	• Clean with a solution of warm water and a mild detergent. • Heat disinfects in a baby bottle steam disinfector or in the microwave oven.		• **Single-use per patient.** • Should not be shared between patients.[5]
Ambubag and mask	• Clean with enzymatic cleaner and • Sterilize with steam (if possible) or Ethylene Oxide (ensure adequate aeration)[10] OR • High-level disinfection with 2% glutaraldehyde for 20-30 minutes contact time or • 0.5% hypochlorite or • 7.5% hydrogen peroxide or • Peracetic Acid (< 1%) for the appropriate contact time[9]		Disposable preferred
Blood pressure cuff	• Clean with a detergent and water • Wipe with 70% alcohol	• Dedicated Blood pressure machine and cuff • Clean with detergent and water • Wipe with 70% alcohol	
Bedpans / urinals	• Place in bedpan washer (Washer-disinfector ≥ 80°C x 1 min) OR • Clean with non-abrasive cleaner • Rinse with clean water and dry • Wipe with hypochlorite solution (1:1000 ppm/ 0.1 – 0.5%) • Store inverted on rack	• Place in bedpan washer (Heat washer/ disinfector > 80°C x 1 min) or • Clean with non-abrasive cleaner • Rinse with clean water and dry • Wipe with hypochlorite (1:1000 ppm/ 0.1-0.5%) • Steam sterilizes for patients with *C. difficile* • Store inverted on rack	Never soak bedpans/ urinals.
Baby feeding bottle	• Wash bottles and teats using detergent and water • Use coarse salt to clean teats • Clean bottle with a bottle brush • Rinse bottles and teats well • Disinfect by submerging in a freshly made hypochlorite solution (125 ppm for 30 minutes/ 0.01%) or [2,9] • Thermal disinfection: 90° C for 1 minute or 80° C for 10 min • Send to CSSD to be steam sterilised (depending on the bottle)	• Thermal disinfection: 90° C for 1 minute or 80° C for 10 minutes • Send to CSSD to be steam sterilised (depending on the bottle)	• No bottles to be added during the disinfecting / sterilising period • Cold sterilisation: only use weak hypochlorite solutions (125 ppm) [2,9] • Diluted sodium dichloroisocyanurate tablets are used in some NICUs in Mauritius

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Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Bowls / Basins (Patient washing)	• Use non-abrasive detergent and water • Disinfect with hypochlorite (1:1000 ppm/0,5%) • Clean after each use • Store dry and inverted. (discard if damaged)	Provide an individual bowl which is returned to the isolation area once cleaned and disinfected after each use • Use detergent and water to clean • After cleaning wipe with hypochlorite solution (1:1000 ppm/ 0,5%) or • Heat disinfects (if indicated)	Autoclave if contamination risk is high
Bowl (quivette) used for mouthcare	• Wash with a detergent and water • Sterilize	• Wash with a detergent and water • Sterilize	
Bin used for collection/disposal of used diapers	• Use detergent and water • Disinfect with hypochlorite (1:1000 ppm/0,5%)	• Use detergent and water • Disinfect with hypochlorite (1:1000 ppm/0,5%)	
CPAP mask	• Single-use per patient preferred • Wash with detergent and water daily • Rinse and dry	• Single-use	• There are disposable and re-usable items available (some up to 5 uses) Have to be managed according to the manufacturer's guidelines
Ear Pieces (Auroscopes)	• Wash with detergent and water • Rinse and dry • Wipe with 70 % alcohol surface disinfectant • Store dry	Dedicated equipment	Do not soak in a disinfectant
Endoscopes • Cystoscopes • Bronchoscopes	• Clean with an enzymatic detergent • Place in a high-level disinfectant e.g. Glutaraldehyde (>2% for 20 – 90 minutes at 20 - 25° C) or Orthophtadehyde (0.55% for 12 minute at 20°C) (according to the manufactures instructions)	No special considerations	NOTE: • Heat tolerant: Heat sterilise • Heat sensitive: High level chemical disinfectant with compatible agent.[3]

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Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Feeding utensils (neonates)	• Clean with detergent and water • High level disinfection using a thermal disinfection: 90°C for 1 minute or 80°C for 10 minutes		
Flow sensors	• Single use preferred Re-usable: • Automated processes are preferred e.g. ultrasonic cleaner Manual: • Clean with an enzymatic detergent and water immediately after use • Do not use brushes inside the flow sensor • Rinse tubes properly in the detergent solution and then with clean distilled water • Allow to dry • Disinfect in Orthophtadehyde (Cidex OPA) • Rinse with clean distilled water • Allow to dry		• Single use is preferred • Autoclavable flow sensors has a limited life span[6]
Glucometer	• Wipe with a damp cloth with detergent mixed in water • Disinfect with 70% alcohol		
Humidifiers	• Empty daily • Clean with warm water and detergent • Heat disinfects after each patient	Single use	Wash with detergent and water before heat disinfection
Incubator /radiant warmer	• Clean all detachable parts thoroughly with a detergent and water	• Clean with a detergent and water • Disinfect with 70% alcohol or hypochlorite 1:125 ppm • Allow to aerate for approximately 6 hours[2]	Long-term care infants should be re-placed in clean incubators every 7 days
Incubator humidifier water reservoir	• Empty, wash, dry and refill every 24 hours		
Infusion pumps	• Clean with a detergent and water • Disinfect with alcohol 70% or hypochlorite solution 0,5% (depending on the manufacturers instruction)		Wipe daily with a detergent and water or detergent wipe while still in use

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Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Kidney dishes	Aseptic procedure: • Clean with a detergent and sterilise Non-aseptic procedures (e.g. to carry injections) • Clean with a detergent and water	Non-aseptic procedures • Clean with a detergent and water • Disinfect with 70% alcohol or hypochlorite (1:1000 ppm or 0,5%) • Autoclave	
Laryngeal mask airway	Single use OR • Wash thoroughly with detergent and water solution • Rinse and dry • Autoclave	Single use	
Laryngoscope Blade	Blade: • Disassemble • Clean with a detergent and water (and soft brush if necessary • Rinse and dry • Disinfect/sterilize • Autoclave (according to the manufactures guideline) OR • Immerse in 70% alcohol and soak for 10 minutes	The same as for routine cleaning • If possible, send blades to CSSD for sterilisation (According to manufacturer's guidelines) • Single use is available	• Store safely to prevent recontamination • Single use is available[2,7]
Laryngoscopes Handle	• Wipe handle with detergent and water • Wipe with 70% alcohol		
Mattress	• Clean with detergent and water and dry thoroughly • Disinfect with 70% alcohol or hypochlorite 0.5% on discharge of patients	• Clean with detergent and water and dry thoroughly • Disinfect with 70% alcohol or hypochlorite 0.5% on discharge of patients	Ensure mattresses have removable and washable covers
Measuring tape	• Clean with detergent and water and wipe with alcohol 70% daily • Wipe with 70% alcohol after each patient use	• Clean with detergent and water and wipe with alcohol 70% daily	
Nasal airway	Single-use	Single-use	Single-use [7]
Ophthalmoscope	• Clean with detergent and water • Dry • Disinfect with 70% alcohol • Wipe lens with a soft cloth	• Clean with detergent and water • Dry • Disinfect with 70% alcohol • Wipe lens with a soft cloth	When not in use keep dry and covered

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Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Oxygen flow meter	• Clean with a damp cloth with detergent and water • Do not spray anything on the flowmeter	• Clean with a damp cloth with detergent and water • Wipe with 70% alcohol	• Never autoclave the flowmeter, or gas sterilize it with ethylene oxide (EtO) • Never immerse flowmeter in liquid[8]
Oxygen saturation probe	• Wash with detergent and water solution daily if used • Rinse and dry	• Wash with detergent and water solution daily if used • Rinse and dry • Wipe with 70% alcohol	
Phototherapy units	• Clean with a detergent and water • Disinfect with alcohol 70% or hypochlorite solution 0,5% (depending on the manufacturers instruction)		Wipe daily with a detergent and water or detergent wipe while still in use
Procedure sets	• Clean with detergent and water • Steam sterilizes (autoclave)		
Procedure trolleys	• Wipe with detergent and water • Dry properly • Wipe with 70% alcohol	• Wipe with a detergent and water • Dry properly • Wipe with 70% alcohol	
Proctoscopes	• Clean with detergent and water • Autoclave / pasteurise / high level disinfection	• Clean with detergent and water • Autoclave / pasteurise / high level disinfection	Sterilised or use high level disinfectant (glutaraldehyde or Orthophtadehyde) after each patient
Pulse Oximeter	• Clean with detergent and water • Disinfect with either 70% alcohol or hypochlorite 0,5% depending on the manufacturer's instruction	• Clean with detergent and water • Disinfect with either 70% alcohol or hypochlorite 0,5% depending on the manufacturer's instruction	Wipe daily with detergent and water or detergent wipe while in use
Stethoscope	• Wipe with detergent and water • Wipe with 70% alcohol	• Wipe with detergent and water • Wipe with 70% alcohol	
Suction bottles (Re-usable bottles without receptacle liner)	Wash with detergent and water after each patient use or when emptied • Rinse and dry • Pasteurise / autoclave / high level disinfectant OR • Rinse in hypochlorite solution (1:1000 ppm/0,5%) • Rinse and dry	Wash with detergent and water after each patient use or when emptied • Rinse and dry • Autoclave/high level disinfectant OR • Rinse in hypochlorite solution (1:1000 ppm/0,5%) • Rinse and dry	

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Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Suction container (With receptacle liner)	Disposable receptacle liners are discarded as healthcare risk waste when ¾ full • Wash container with detergent and water after each patient use and when visibly soiled • Rinse and dry • Line container with disposable receptor liner, single use item	Disposable receptacle liners are discarded as healthcare risk waste when ¾ full • Wash container with detergent and water when visibly soiled • Rinse and dry • Line container with disposable receptor liner, single use item Wipe down daily with a hypochlorite solution (1:1000 ppm) as with terminal disinfection	Discard according to the healthcare risk waste (HCRW) guidelines/policy and that of the HCRW contractor • Double bag disposable receptor liners if not using a rigid container, because of the possibility of leakage • Note: Never leave fluid in reservoir if not used. Ensure regular change of receptacle liner if it is a long-term patient with limited secretions
Suction tubing	• Single use preferred • PVC suction tubing: single use only • Silicone tubing: re-use is not recommended • If re-used, it must be cleaned properly with an enzymatic cleaner and autoclaved/ sterilised after cleaning	Single-use	Do not use glutaraldehyde on respiratory equipment
Syringe pumps	• Clean with a detergent and water • Disinfect with alcohol 70% (depending on the manufacturers instruction)		Wipe daily with a detergent and water or detergent wipe while still in use
Thermometer	• Clean with detergent and water • Disinfect with alcohol 70%		Never soak thermometers in disinfectants
Tonometer	• Wipe with a detergent and water • Disinfect with 70% isopropyl alcohol • Air dry and rinse with clean water • Allow to dry		
T-tube for: Nebulising Oxygen therapy (Single use for the same patient)	• Wash with detergent and water solution after use • Rinse and dry	• Single use	• Single use for the same patient

Manufacturer's instructions for product, concentration and contact time must always be followed			
Equipment	**Routine method Non-infected patients**	**Alternative method Infected patient/ contaminated with blood or bodily fluids**	**Comments**
Ventilators Circuits	• Single use preferred • Re-usable circuits: Wash with detergent and water, rinse and dry • Steam sterilization (autoclave) (depending on manufacturer's instructions) or • Heat disinfects (80° C x 3 min)	• Single use	• Change circuits every 7 days or according to manufacturer's guidelines • Use new tubing for each patient • **Never use glutaraldehyde to disinfect respiratory equipment**
Ventilators Temperature Probes	Re-usable: • Wash with water and detergent after each patient and sterilise or high level disinfect		
Weighing scales	• Clean with detergent and water • Wipe with 70% alcohol		
Yankhauer suction catheter	Single use preferred	Single use	

Adapted from: Mehtar, S., 2023. Understanding IPC. 2nd Edition. Juta and Company[2]

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